UNITED STATES PATENT AND TRADEMARK OFFICE

C 1C

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,120	07/18/2001	Dana Ault-Riche	25885-1751	1666

24961 7590 11/10/2005

HELLER EHRMAN LLP
4350 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122-1246

EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,120	AULT-RICHE ET AL.	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 0805*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,25-37,49-54,93-95 and 99-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,25-37,49-54,93-95 and 99-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application and Claims Status

1. Applicant's amendment and response filed 08/08/2005 is acknowledged and entered. Claims 1, 11, 17, 18, 21-23, 34, and 35 have been amended. Claims 100-102 have been added.

2. The amendment filed on 2/12/2004: cancelled claim 24, and amended claims 1, 4, 8, 9, 11-14, 16, 20, 23, 25-35, 49, 50, 53, and 93-95.

3. The amendment filed on 12/27/2002: cancelled claims 38-48, 55-92, and 96-98, and added claim 99.

4. Claims 1-23, 25-37, 49-54, 93-95, and 99-102 are pending.

Priority

5. This instant application claims benefit to a provisional application of 60/219,183 filed 07/19/2000. This instant application is granted the benefit of priority for 60/219,183 under 35 U.S.C 119(e).

Information Disclosure Statement

6. The information disclosure statement (IDS) filed on 08/08/2005 has been reviewed, and its references have been considered as noted on PTO-1449 form.

7. Claims 1-23, 25-37, 49-54, 93-95, and 99-102 are under consideration in this Office Action.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-9, 11-23, 25-36, 93 and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al. (US Patent 5,573,905).

The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a set containing a plurality of oligonucleotides.

Each capture agent specifically binds to a polypeptide. The collection of capture agents comprises at least M different sets of captures agents, and M is at least 10, which is the number of different sequences of amino acids encoded by the oligonucleotides for which capture agents in the collection are specific. Each set of capture agents is specific for the same sequence of amino acids, and all sets of capture agents specifically bind to different sequences of amino acids encoded by the oligonucleotides.

Each member of the set of oligonucleotide comprises 1) a sequence of nucleotides E_m that encodes a preselected polypeptide; 2) the preselected polypeptide bind to the capture agents; 3) the oligonucleotides are single-stranded, double-stranded, or partially double-stranded; 4) the oligonucleotide comprises the formula 5'- E_m-3'; 5) each E_m encodes a sequence of amino acids to which a capture agent in the collection specifically binds and the sequence of amino acids is unique in a set; and 6) m is at least 10.

Lerner et al. disclose a plurality of products (see e.g. Abstract; col. 2, lines 45-67). These products include an encoded combinatorial library, wherein each composition of the library comprises a chemical polymer and an identifier nucleotide sequences that defines the structure of the chemical polymer, and the binding reaction complexes (see e.g. col. 2, lines 45-67; col. 3, line 26-40; col. 4, line 10 thru col. 8, line 53; col. 9, lines 40-55; col. 15, lines 15-57). The

composition (refers to instant claimed set of oligonucleotide) comprises the identifier nucleotide sequences, a linker molecule, and a chemical polymer (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 4, line 29 thru col. 8, line 53; col. 11, line 61 thru col. 13, line 12). The identifier nucleotide sequences comprise a coding region (refers to instant claimed E_m) that is flank by two different PCR (polymerase chain reaction) primers (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 5, line 49 thru col. 6, line 9). The primers comprises nucleotide sequences that provide polymerase chain reaction primer binding sites for amplification (refers to the instant claimed common region (variable C in the formula 5'-C-E_m-3' of claim 25), and the instant claimed variable D in the formula 5'-D_n-E_m-3' of claim 26), and restriction sites (refers to the instant claimed divider region) such as incorporation of a biotinylated nucleotide (refers to instant claims 11-12, 15, 16, and 36) (see e.g. col. 6, line 66 thru col. 7, line 45). The length of the primer is at least 10 nucleotides (refers to instant claimed n=10 of claims 26, 28-32, 94, and 95) (see e.g. ref. #P1 and P2 of fig. 2). The length of the coding region varies depending on the complexity of the library that is the chemical polymer, and in general the number of nucleotides ranges is from about 2 to about 15 (refers to instant claimed m=10, and instant claims 13, 14, 23, 24, 34, and 35) (see e.g. col. 4, lines 29-40; col. 5, lines 49-58; col. 6, lines 2-9, and lines 56-65). The chemical polymer includes polymer such as peptide polymers and the length of the polymer varies, which is typically 4 to 50 (refers to instant claimed M=10, and instant claims 17, 18, 21, 22, and 27-29) (see e.g. col. 4, lines 37-52; col. 8, line 63 thru col. 9, line 14). Additionally, the binding reaction complexes (refers to instant claimed combination) are produced by the binding interaction between the chemical polymer of the library and a biologically active molecule (refers to instant claimed capture agent) wherein the binding interaction includes interaction such

as antibodies to antigen (refers to instant claims 2, 4, 33, and 93) (see e.g. col. 2, lines 61-67; col. 3, line 26-40; col. 15, lines 15-57). The biologically active molecule can be affixed to a solid support (refers to instant claims 5, and 6) (see e.g. col. 16, lines 42-67). The solid support includes supports such as beads, and microtiter plate wells (refers to claims 3, 7-9, 19, and 20) (see e.g. col. 17, lines 11-21). The products of Lerner et al. anticipate the presently claimed invention.

Furthermore regarding the amendments of claim 1 that recite the '*combination comprises two collections*', i.e. '*a collection of capture agents*' and '*a collection of oligonucleotides*', these limitations are still anticipated by the products of Lerner et al. Lerner et al. discloses a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides) and a binding reaction admixture wherein the admixture comprises a 'mixture' of biological active molecules (refers to the instant claimed collection of capture agents) (see e.g. col. 15, lines 34-40 and lines 58-67). The binding reaction admixture comprises a 'mixture' of heterogeneous biological active molecules or homogeneous biological active molecules (refers to new limitations that the collection of capture agents comprises sets of capture agents)(see e.g. col. 15, lines 58-67).

10. Claims 1, 2, 11, 12, 25, 26, 36, 49-51, and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Dower et al. (US Patent 5,639,603).

The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a set containing a plurality of oligonucleotides.

Each capture agent specifically binds to a polypeptide. The collection of capture agents comprises at least M different sets of captures agents, and M is at least 10, which is the number of different sequences of amino acids encoded by the oligonucleotides for which capture agents in the collection are specific. Each set of capture agents is specific for the

same sequence of amino acids, and all sets of capture agents specifically bind to different sequences of amino acids encoded by the oligonucleotides.

Each member of the set of oligonucleotide comprises 1) a sequence of nucleotides E_m that encodes a preselected polypeptide; 2) the preselected polypeptide bind to the capture agents; 3) the oligonucleotides are single-stranded, double-stranded, or partially double-stranded; 4) the oligonucleotide comprises the formula 5'- E_m-3'; 5) each E_m encodes a sequence of amino acids to which a capture agent in the collection specifically binds and the sequence of amino acids is unique in a set; and 6) m is at least 10.

Dower et al. disclose a plurality of products (see e.g. Abstract; col. 1, lines 13-21). The products include encoded synthetic chemical libraries and the binding reaction complexes (see e.g. col. 1, lines 13-21; col. 3, line 66 to col. 4, line 18; col. 4, line 66 thru col. 5, line 11; col. 26, lines 12-42). The encoded synthetic chemical libraries (refers to instant claimed set of oligonucleotide) comprise beads, identifier tags, and oligomer (see e.g. col. 3, line 66 to col. 4, line 18; col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42; col. 44, line 61 to col. 45, line 39). The identifier tags are oligonucleotides (see e.g. col. 16, lines 15-24, and lines 48-63). Each oligonucleotide tag comprises an amplification sites (refers to the instant claimed common region/variable C), monomer specific information/coding site (refers to instant claimed E_m), a spacer segment of variable length that distant the coding site from the amplification sites (refers to instant claimed divider region), and the order-of-reaction information (refers to the instant claimed variable D) (refers to instant claims 11, 12, 25, 26, and 99) (see e.g. col. 17, lines 42-53; col. 18, line 28 thru col. 19, line 46). Each oligonucleotide tag has the length with a range of 50 to 150 nucleotides and is singled stranded oligonucleotide (refers to claim 36) (see e.g. col. 17, lines 42-53; col. 18, lines 4-9, and lines 49-63). The oligomer comprises a plurality of different peptide sequences (see e.g. col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42). The binding reaction complexes are produced by the binding interaction between the oligomers and the receptors (refers to instant claimed capture agent) such as antibodies (refers to instant claim

2) (see e.g. col. 8, lines 23-46; col. 31, lines 11-27, and lines 36-40). The binding reaction complexes were sorted by using fluorescence activated cell-sorting instrument (refers to instant claims 49-51) (see e.g. col. 26, lines 32-40; col. 31, lines 54-63; col. 45, lines 1-7). Thus the products of Dower et al. anticipate the presently claimed combination and system.

Furthermore regarding the amendments of claim 1 that recite the '*combination comprises two collections*', i.e. '*a collection of capture agents*' and '*a collection of oligonucleotides*', these limitations are still anticipated by the products of Dower et al. Dower et al. discloses a 'mixture' of the combinatorial library (refers to the instant claimed collection of oligonucleotides) and a binding reaction admixture wherein the admixture comprises a 'mixture' of receptors (refers to the instant claimed collection of capture agents)(see e.g. col. 31, lines 54-60). The binding reaction admixture comprises complex mixtures such as families of receptors (refers to new limitations that the collection of capture agents comprises sets of capture agents)(see e.g. col. 34, lines 55-67).

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 1-9, 11-23, 25-36, 49-51, and 93-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. (US Patent 5,573,905) and Dower et al. (US Patent 5,639,603).

The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a set containing a plurality of oligonucleotides.

Each capture agent specifically binds to a polypeptide. The collection of capture agents comprises at least M different sets of captures agents, and M is at least 10, which is the number of different sequences of amino acids encoded by the oligonucleotides for which

capture agents in the collection are specific. Each set of capture agents is specific for the same sequence of amino acids, and all sets of capture agents specifically bind to different sequences of amino acids encoded by the oligonucleotides.

Each member of the set of oligonucleotide comprises 1) a sequence of nucleotides E_m that encodes a preselected polypeptide; 2) the preselected polypeptide bind to the capture agents; 3) the oligonucleotides are single-stranded, double-stranded, or partially double-stranded; 4) the oligonucleotide comprises the formula 5'- E_m-3'; 5) each E_m encodes a sequence of amino acids to which a capture agent in the collection specifically binds and the sequence of amino acids is unique in a set; and 6) m is at least 10.

Lerner et al. disclose a plurality of products (see e.g. Abstract; col. 2, lines 45-67). These products include an encoded combinatorial library, wherein each composition of the library comprises a chemical polymer and an identifier nucleotide sequences that defines the structure of the chemical polymer, and the binding reaction complexes (see e.g. col. 2, lines 45-67; col. 3, line 26-40; col. 4, line 10 thru col. 8, line 53; col. 9, lines 40-55; col. 15, lines 15-57). The composition (refers to instant claimed set of oligonucleotide) comprises the identifier nucleotide sequences, a linker molecule, and a chemical polymer (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 4, line 29 thru col. 8, line 53; col. 11, line 61 thru col. 13, line 12). The identifier nucleotide sequences comprise a coding region (refers to instant claimed E_m) that is flank by two different PCR (polymerase chain reaction) primers (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 5, line 49 thru col. 6, line 9). The primers comprises nucleotide sequences that provide polymerase chain reaction primer binding sites for amplification (refers to the instant claimed common region (variable C in the formula 5'-C-E_m-3' of claim 25), and the instant claimed variable D in the formula 5'-D_n-E_m-3' of claim 26), and restriction sites (refers to the instant claimed divider region) such as incorporation of a biotinylated nucleotide (refers to instant claims 11-12, 15, 16, and 36) (see e.g. col. 6, line 66 thru col. 7, line 45). The length of the primer is at least 10 nucleotides (refers to instant claimed n=10 of claims 26, 28-32, 94, and 95)

(see e.g. ref. #P1 and P2 of fig. 2). The length of the coding region varies depending on the complexity of the library that is the chemical polymer, and in general the number of nucleotides ranges is from about 2 to about 15 (refers to instant claimed m=10, and instant claims 13, 14, 23, 24, 34, and 35) (see e.g. col. 4, lines 29-40; col. 5, lines 49-58; col. 6, lines 2-9, and lines 56-65). The chemical polymer includes polymer such as peptide polymers and the length of the polymer varies, which is typically 4 to 50 (refers to instant claimed M=10, and instant claims 17, 18, 21, 22, and 27-29) (see e.g. col. 4, lines 37-52; col. 8, line 63 thru col. 9, line 14). Additionally, the binding reaction complexes (refers to instant claimed combination) are produced by the binding interaction between the chemical polymer of the library and a biologically active molecule (refers to instant claimed capture agent) wherein the binding interaction includes interaction such as antibodies to antigen (refers to instant claims 2, 4, 33, and 93) (see e.g. col. 2, lines 61-67; col. 3, line 26-40; col. 15, lines 15-57). The biologically active molecule can be affixed to a solid support (refers to instant claims 5, and 6) (see e.g. col. 16, lines 42-67). The solid support includes supports such as beads, and microtiter plate wells (refers to claims 3, 7-9, 19, and 20) (see e.g. col. 17, lines 11-21).

Furthermore regarding the amendments of claim 1 that recite the '*combination comprises two collections*', i.e. '*a collection of capture agents*' and '*a collection of oligonucleotides*', these limitations are still disclosed by the products of Lerner et al. Lerner et al. discloses a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides) and a binding reaction admixture wherein the admixture comprises a 'mixture' of biological active molecules (refers to the instant claimed collection of capture agents) (see e.g. col. 15, lines 34-40 and lines 58-67). The binding reaction admixture comprises a 'mixture' of heterogeneous

biological active molecules or homogeneous biological active molecules (refers to new limitations that the collection of capture agents comprises sets of capture agents)(see e.g. col. 15, lines 58-67).

The products of Lerner et al. differ from the presently claimed invention by failing to include a computer system with software for analyzing results of sorting.

Dower et al. disclose a plurality of products (see e.g. Abstract; col. 1, lines 13-21). The products include encoded synthetic chemical libraries and the binding reaction complexes (see e.g. col. 1, lines 13-21; col. 3, line 66 to col. 4, line 18; col. 4, line 66 thru col. 5, line 11; col. 26, lines 12-42). The encoded synthetic chemical libraries (refers to instant claimed set of oligonucleotide) comprise beads, identifier tags, and oligomer (see e.g. col. 3, line 66 to col. 4, line 18; col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42; col. 44, line 61 to col. 45, line 39). The identifier tags are oligonucleotides (see e.g. col. 16, lines 15-24, and lines 48-63). Each oligonucleotide tag comprises an amplification sites (refers to the instant claimed common region/variable C), monomer specific information/coding site (refers to instant claimed E_m), a spacer segment of variable length that distant the coding site from the amplification sites (refers to instant claimed divider region), and the order-of-reaction information (refers to the instant claimed variable D) (refers to instant claims 11, 12, 25, 26, and 99) (see e.g. col. 17, lines 42-53; col. 18, line 28 thru col. 19, line 46). Each oligonucleotide tag has the length with a range of 50 to 150 nucleotides and is singled stranded oligonucleotide (refers to claim 36) (see e.g. col. 17, lines 42-53; col. 18, lines 4-9, and lines 49-63). The oligomer comprises a plurality of different peptide sequences (see e.g. col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42). The binding reaction complexes are produced by the binding interaction between the oligomers and

the receptors (refers to instant claimed capture agent) such as antibodies (refers to instant claim 2) (see e.g. col. 8, lines 23-46; col. 31, lines 11-27, and lines 36-40). The binding reaction complexes were sorted by using fluorescence activated cell-sorting instrument (refers to instant claims 49-51) (see e.g. col. 26, lines 32-40; col. 31, lines 54-63; col. 45, lines 1-7).

Furthermore regarding the amendments of claim 1 that recite the '*combination comprises two collections*', i.e. '*a collection of capture agents*' and '*a collection of oligonucleotides*', these limitations are still anticipated by the products of Dower et al. Dower et al. discloses a binding reaction admixture wherein the admixture comprises a 'mixture' of receptors (refers to the instant claimed collection of capture agents) and a 'mixture' of the combinatorial library (refers to the instant claimed collection of oligonucleotides)(see e.g. col. 31, lines 54-60).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a computer system with software for analyzing results of sorting as taught by Dower et al. in the products of Lerner et al. One of ordinary skill in the art would have been motivated to include a computer system with software for analyzing results of sorting in the products of Lerner et al. since Lerner et al. disclose that any separation means is use to selectively isolate the binding reaction complex from binding reaction mixture (Lerner: col. 16, lines 36-41) and Dower et al. disclose that fluorescence activated cell-sorting instrument is a known in the art as a means of isolating the binding reaction complex from binding reaction mixture (Dower: col. 31, lines 50-67). Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a computer system with software for analyzing results of sorting as taught by Dower et al. in the products of Lerner et al. Additionally, both Lerner et al. and Dower et al. disclose the assay method wherein libraries are

screened for its binding ability to the receptors of interest (Lerner: col. 15, lines 27-49; Dower: col. 31, lines 28-40. Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Lerner et al. and Dower et al. because Dower et al. disclose by example the success of using the fluorescence activated cell-sorting instrument for analyzing results of sorting (Dower: col. 47, lines 8-29).

13. Claims 1-9, 11-23, 25-36, 49-54, and 93-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. (US Patent 5,573,905) and Iris et al. (US Patent 6,403,309 B1).

The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a set containing a plurality of oligonucleotides.

Each capture agent specifically binds to a polypeptide. The collection of capture agents comprises at least M different sets of captures agents, and M is at least 10, which is the number of different sequences of amino acids encoded by the oligonucleotides for which capture agents in the collection are specific. Each set of capture agents is specific for the same sequence of amino acids, and all sets of capture agents specifically bind to different sequences of amino acids encoded by the oligonucleotides.

Each member of the set of oligonucleotide comprises 1) a sequence of nucleotides E_m that encodes a preselected polypeptide; 2) the preselected polypeptide bind to the capture agents; 3) the oligonucleotides are single-stranded, double-stranded, or partially double-stranded; 4) the oligonucleotide comprises the formula 5'- E_m-3'; 5) each E_m encodes a sequence of amino acids to which a capture agent in the collection specifically binds and the sequence of amino acids is unique in a set; and 6) m is at least 10.

Lerner et al. disclose a plurality of products (see e.g. Abstract; col. 2, lines 45-67). These products include an encoded combinatorial library, wherein each composition of the library comprises a chemical polymer and an identifier nucleotide sequences that defines the structure of the chemical polymer, and the binding reaction complexes (see e.g. col. 2, lines 45-67; col. 3, line 26-40; col. 4, line 10 thru col. 8, line 53; col. 9, lines 40-55; col. 15, lines 15-57). The composition (refers to instant claimed set of oligonucleotide) comprises the identifier nucleotide sequences, a linker molecule, and a chemical polymer (see e.g. col. 3, lines 15-20; col. 4, lines

18-27; col. 4, line 29 thru col. 8, line 53; col. 11, line 61 thru col. 13, line 12). The identifier nucleotide sequences comprise a coding region (refers to instant claimed E_m) that is flank by two different PCR (polymerase chain reaction) primers (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 5, line 49 thru col. 6, line 9). The primers comprises nucleotide sequences that provide polymerase chain reaction primer binding sites for amplification (refers to the instant claimed common region (variable C in the formula 5'-C-E_m-3' of claim 25), and the instant claimed variable D in the formula 5'-D_n-E_m-3' of claim 26), and restriction sites (refers to the instant claimed divider region) such as incorporation of a biotinylated nucleotide (refers to instant claims 11-12, 15, 16, and 36) (see e.g. col. 6, line 66 thru col. 7, line 45). The length of the primer is at least 10 nucleotides (refers to instant claimed n=10 of claims 26, 28-32, 94, and 95) (see e.g. ref. #P1 and P2 of fig. 2). The length of the coding region varies depending on the complexity of the library that is the chemical polymer, and in general the number of nucleotides ranges is from about 2 to about 15 (refers to instant claimed m=10, and instant claims 13, 14, 23, 24, 34, and 35) (see e.g. col. 4, lines 29-40; col. 5, lines 49-58; col. 6, lines 2-9, and lines 56-65). The chemical polymer includes polymer such as peptide polymers and the length of the polymer varies, which is typically 4 to 50 (refers to instant claimed M=10, and instant claims 17, 18, 21, 22, and 27-29) (see e.g. col. 4, lines 37-52; col. 8, line 63 thru col. 9, line 14). Additionally, the binding reaction complexes (refers to instant claimed combination) are produced by the binding interaction between the chemical polymer of the library and a biologically active molecule (refers to instant claimed capture agent) wherein the binding interaction includes interaction such as antibodies to antigen (refers to instant claims 2, 4, 33, and 93) (see e.g. col. 2, lines 61-67; col. 3, line 26-40; col. 15, lines 15-57). The biologically active molecule can be affixed to a solid

support (refers to instant claims 5, and 6) (see e.g. col. 16, lines 42-67). The solid support includes supports such as beads, and microtiter plate wells (refers to claims 3, 7-9, 19, and 20) (see e.g. col. 17, lines 11-21).

Furthermore regarding the amendments of claim 1 that recite the '*combination comprises two collections*', i.e. '*a collection of capture agents*' and '*a collection of oligonucleotides*', these limitations are still disclosed by the products of Lerner et al. Lerner et al. discloses a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides) and a binding reaction admixture wherein the admixture comprises a 'mixture' of biological active molecules (refers to the instant claimed collection of capture agents) (see e.g. col. 15, lines 34-40 and lines 58-67). The binding reaction admixture comprises a 'mixture' of heterogeneous biological active molecules or homogeneous biological active molecules (refers to new limitations that the collection of capture agents comprises sets of capture agents)(see e.g. col. 15, lines 58-67).

The products of Lerner et al. differ from the presently claimed invention by failing to include a computer system with software for analyzing results of sorting.

Iris et al. discloses an array of antibody that captures oligonucleotide probes labeled with peptide tags (see e.g. Abstract; col. 1, lines 14-18; col. 2, lines 34-47). The solid phase surface comprises a plurality of loci (refers to the presently claimed addressable array), wherein each locus comprises an antibody specific to one or more of the peptides of the peptide label oligonucleotide probes (see e.g. col. 6, lines 28-31; col. 22, lines 23-29). The peptide tags are specific to the antibodies of the array (see e.g. col. 21, lines 29-39). Further, the oligonucleotide probes may be first hybridized to a target DNA before being capture by the addressable antibody

arrays (see e.g. col. 15, lines 32-67 to col. 16, lines 1-11). Additionally, the array of Iris et al. comprises a computer that generates and stores the arrayed pattern of the array (refers to the presently claimed computer system and claim 53) (see e.g. col. 23, lines 18-25).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a computer system with software for analyzing results of sorting as taught by Iris et al. in the products of Lerner et al. One of ordinary skill in the art would have been motivated to include a computer system with software for analyzing results of sorting in the products of Lerner et al. since Lerner et al. disclose that any separation means is use to selectively isolate the binding reaction complex from binding reaction mixture wherein the receptors are bound to the solid support (Lerner: col. 16, lines 36-41, and lines 56-67) and Iris et al. disclose any method known in the art can be used for the visualization or detection of the binding reaction complex on an antibody array (Iris: col. 19, lines 27-37). Additionally, both Lerner et al. and Iris et al. disclose an array of receptors (Lerner: col. 17, lines 11-21; Iris: col. 22, line 23 thru col. 23, line 31). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Lerner et al. and Iris et al. because Iris et al. disclose by example the success of fluorescent detection of binding reaction complex on an antibody array (Iris: col. 27, line 15 thru col. 30, line 10).

New Rejection(s) – Necessitated by Amendment

Claim Objections

14. Claims 11, 25, 26, and 99 are objected to because of the following informalities:

a. Claim 11 is objected to because of the "*$$*" between the word '*library*', and '*and*' in line 4. It is unclear is this is a typographical error or a 'variable' for an additional limitation. In order to further prosecution, the "*$$*" is interpreted as a typographical error.

b. Claim 25 is objected to because the formula is written as "*5' C-Em 3'*". The formula as previously presented is"*5'-C-E_m-3'*" wherein '*m*' is a subscript of the variable '*E*', i.e. '*m*' further define the variable '*E*'. It unclear if '*m*' is an additional component or typographical error. In order to further prosecution, the "*m*" is interpreted as a typographical error.

c. Claim 26 is objected to because the formula is written as "*5'-Dn-Em- 3'*". The formula as previously presented is"*5'-D_n-E_m-3'*" wherein '*m*' is a subscript of the variable '*E*', i.e. '*m*' further define the variable '*E*', and '*n*' is a subscript of the variable '*D*', i.e. '*m*' further define the variable '*D*'. It unclear if '*m*' and '*n*' are additional components or typographical errors. In order to further prosecution, the "*m*" and '*n*' are interpreted as typographical errors.

d. Claim 99 is objected to because the formula is written as "*5' C-Dn-Em 3'*". The formula as previously presented is"*5'-C-D_n-E_m-3'*" wherein '*m*' is a subscript of the variable '*E*', i.e. '*m*' further define the variable '*E*', and '*n*' is a subscript of the variable '*D*', i.e. '*m*' further define the variable '*D*'. It unclear if '*m*' and '*n*' are additional components or typographical errors. In order to further prosecution, the "*m*" and '*n*' are interpreted as typographical errors.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claim 100 is rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al. (US Patent 5,573,905).

> *The instant invention recites a kit, which is interpreted as "a composition of matters"(which is defined as product, wherein the discrete physical structures or materials is the distinguishing characteristic. A composition may be a molecule(s), compound(s), solution(s), mixture(s), alloy(s), atom(s), etc.). The composition comprises a combination and optionally instructions for use of the collections in the combination for screening or identifying nucleic acids, proteins, and other molecules.*
>
> *In the instant claimed composition, the limitation of instructions is define by the term "optionally" and the broadest definition of the term "optionally" is applied, i.e. it is a choice. Thus, the instant claimed composition is broadly interpreted to* ***either*** *include the limitation of instructions* ***or*** *not, i.e. it can be interpreted that the limitation of instructions is omitted from the instant claimed composition.*

Lerner et al. disclose a plurality of products (see e.g. Abstract; col. 2, lines 45-67). These products include an encoded combinatorial library, wherein each composition of the library comprises a chemical polymer and an identifier nucleotide sequences that defines the structure of the chemical polymer, and the binding reaction complexes (see e.g. col. 2, lines 45-67; col. 3, line 26-40; col. 4, line 10 thru col. 8, line 53; col. 9, lines 40-55; col. 15, lines 15-57). The composition (refers to instant claimed set of oligonucleotide) comprises the identifier nucleotide sequences, a linker molecule, and a chemical polymer (see e.g. col. 3, lines 15-20; col. 4, lines

18-27; col. 4, line 29 thru col. 8, line 53; col. 11, line 61 thru col. 13, line 12). The identifier nucleotide sequences comprise a coding region (refers to instant claimed E_m) that is flank by two different PCR (polymerase chain reaction) primers (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 5, line 49 thru col. 6, line 9). The primers comprises nucleotide sequences that provide polymerase chain reaction primer binding sites for amplification (refers to the instant claimed common region (variable C in the formula 5'-C-E_m-3' of claim 25), and the instant claimed variable D in the formula 5'-D_n-E_m-3' of claim 26), and restriction sites (refers to the instant claimed divider region) such as incorporation of a biotinylated nucleotide (refers to instant claims 11-12, 15, 16, and 36) (see e.g. col. 6, line 66 thru col. 7, line 45). The length of the primer is at least 10 nucleotides (refers to instant claimed n=10 of claims 26, 28-32, 94, and 95) (see e.g. ref. #P1 and P2 of fig. 2). The length of the coding region varies depending on the complexity of the library that is the chemical polymer, and in general the number of nucleotides ranges is from about 2 to about 15 (refers to instant claimed m=10, and instant claims 13, 14, 23, 24, 34, and 35) (see e.g. col. 4, lines 29-40; col. 5, lines 49-58; col. 6, lines 2-9, and lines 56-65). The chemical polymer includes polymer such as peptide polymers and the length of the polymer varies, which is typically 4 to 50 (refers to instant claimed M=10, and instant claims 17, 18, 21, 22, and 27-29) (see e.g. col. 4, lines 37-52; col. 8, line 63 thru col. 9, line 14).

In addition, Lerner et al. discloses a binding reaction admixture (refers to instant claimed combination) wherein the admixture comprises a 'mixture' of biological active molecule (refers to the instant claimed collection of capture agents) and a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides)(see e.g. col. 15, lines 34-40). The binding reaction admixture comprises a 'mixture' of heterogeneous biological active

molecules or homogeneous biological active molecules (refers to new limitations that the collection of capture agents comprises sets of capture agents)(see e.g. col. 15, lines 58-67). The binding reaction complexes are produced by the binding interaction between the chemical polymer of the library and a biologically active molecule of the binding reaction admixture wherein the binding interaction includes interaction such as antibodies to antigen (refers to instant claims 2, 4, 33, and 93) (see e.g. col. 2, lines 61-67; col. 3, line 26-40; col. 15, lines 15-57). The biologically active molecule can be affixed to a solid support (refers to instant claims 5, and 6) (see e.g. col. 16, lines 42-67). The solid support includes supports such as beads, and microtiter plate wells (refers to claims 3, 7-9, 19, and 20) (see e.g. col. 17, lines 11-21).

The instant claimed limitation of '*optionally instructions for use of the collections in the combination for screening or identifying nucleic acids, proteins, and other molecules*' is interpreted that the instant limitation of instructions is omitted from the instant claimed composition.

Therefore, the products of Lerner et al. anticipate the presently claimed invention.

17. Claim 101 is rejected under 35 U.S.C. 102(b) as being anticipated by Dower et al. (US Patent 5,639,603).

> *The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a collection of oligonucleotides. The capture agents specifically bind to preselected polypeptides and are linked directly or indirectly to a solid support that comprises optically-encoded beads. The oligonucleotides encode the preselected polypeptides and are single-stranded, double-stranded, or partially double stranded.*

Dower et al. disclose a plurality of products (see e.g. Abstract; col. 1, lines 13-21). The products include encoded synthetic chemical libraries and the binding reaction complexes (see

e.g. col. 1, lines 13-21; col. 3, line 66 to col. 4, line 18; col. 4, line 66 thru col. 5, line 11; col. 26, lines 12-42). The encoded synthetic chemical libraries (refers to instant claimed set of oligonucleotide) comprise beads, identifier tags, and oligomer (see e.g. col. 3, line 66 to col. 4, line 18; col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42; col. 44, line 61 to col. 45, line 39). The identifier tags are oligonucleotides (see e.g. col. 16, lines 15-24, and lines 48-63). Each oligonucleotide tag comprises an amplification sites, monomer specific information/coding site, a spacer segment of variable length that distant the coding site from the amplification sites, and the order-of-reaction information (see e.g. col. 17, lines 42-53; col. 18, line 28 thru col. 19, line 46). Each oligonucleotide tag has the length with a range of 50 to 150 nucleotides and is singled stranded oligonucleotide (see e.g. col. 17, lines 42-53; col. 18, lines 4-9, and lines 49-63). The oligomer comprises a plurality of different peptide sequences (see e.g. col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42).

In addition, Dower et al. discloses a binding reaction admixture wherein the admixture comprises a 'mixture' of receptors (refers to the instant claimed collection of capture agents) and a 'mixture' of the combinatorial library (refers to the instant claimed collection of oligonucleotides)(see e.g. col. 31, lines 54-60). The binding reaction complexes are produced by the binding interaction between the oligomers and the receptors such as antibodies of the binding reaction admixture (see e.g. col. 8, lines 23-46; col. 31, lines 11-27, and lines 36-40). The receptors are labeled with florescent tag and bind to the oligomer attached to the bead (refers to the claimed limitation of the capture agents are linked indirectly to a solid support that comprises optically-encoded beads)(see e.g. col. 31, lines 57-60). The binding reaction complexes were sorted by using fluorescence activated cell-sorting instrument (see e.g. col. 26, lines 32-40; col.

31, lines 54-63; col. 32, lines 4-29; col. 45, lines 1-7). Thus the products of Dower et al. anticipate the presently claimed combination.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claim 100 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. (US Patent 5,573,905).

> *The instant invention recites a kit, which is interpreted as "a composition of matters"(which is defined as product, wherein the discrete physical structures or materials is the distinguishing characteristic. A composition may be a molecule(s), compound(s), solution(s), mixture(s), alloy(s), atom(s), etc.). The composition comprises a combination and optionally instructions for use of the collections in the combination for screening or identifying nucleic acids, proteins, and other molecules. In the instant claimed composition, the limitation of instructions is define by the term "optionally" and the broadest definition of the term "optionally" is applied, i.e. it is a choice. Thus, the*

instant claimed composition is broadly interpreted to ***either*** *include the limitation of instructions* ***or*** *not, i.e. it can be interpreted that the limitation of instructions is omitted from the instant claimed composition.*

Lerner et al. disclose a plurality of products (see e.g. Abstract; col. 2, lines 45-67). These products include an encoded combinatorial library, wherein each composition of the library comprises a chemical polymer and an identifier nucleotide sequences that defines the structure of the chemical polymer, and the binding reaction complexes (see e.g. col. 2, lines 45-67; col. 3, line 26-40; col. 4, line 10 thru col. 8, line 53; col. 9, lines 40-55; col. 15, lines 15-57). The composition (refers to instant claimed set of oligonucleotide) comprises the identifier nucleotide sequences, a linker molecule, and a chemical polymer (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 4, line 29 thru col. 8, line 53; col. 11, line 61 thru col. 13, line 12). The identifier nucleotide sequences comprise a coding region (refers to instant claimed E_m) that is flank by two different PCR (polymerase chain reaction) primers (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 5, line 49 thru col. 6, line 9). The primers comprises nucleotide sequences that provide polymerase chain reaction primer binding sites for amplification (refers to the instant claimed common region (variable C in the formula 5'-C-E_m-3' of claim 25), and the instant claimed variable D in the formula 5'-D_n-E_m-3' of claim 26), and restriction sites (refers to the instant claimed divider region) such as incorporation of a biotinylated nucleotide (refers to instant claims 11-12, 15, 16, and 36) (see e.g. col. 6, line 66 thru col. 7, line 45). The length of the primer is at least 10 nucleotides (refers to instant claimed n=10 of claims 26, 28-32, 94, and 95) (see e.g. ref. #P1 and P2 of fig. 2). The length of the coding region varies depending on the complexity of the library that is the chemical polymer, and in general the number of nucleotides ranges is from about 2 to about 15 (refers to instant claimed m=10, and instant claims 13, 14, 23,

24, 34, and 35) (see e.g. col. 4, lines 29-40; col. 5, lines 49-58; col. 6, lines 2-9, and lines 56-65). The chemical polymer includes polymer such as peptide polymers and the length of the polymer varies, which is typically 4 to 50 (refers to instant claimed M=10, and instant claims 17, 18, 21, 22, and 27-29) (see e.g. col. 4, lines 37-52; col. 8, line 63 thru col. 9, line 14).

In addition, Lerner et al. discloses a binding reaction admixture (refers to instant claimed combination) wherein the admixture comprises a 'mixture' of biological active molecule (refers to the instant claimed collection of capture agents) and a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides)(see e.g. col. 15, lines 34-40). The binding reaction admixture comprises a 'mixture' of heterogeneous biological active molecules or homogeneous biological active molecules (refers to new limitations that the collection of capture agents comprises sets of capture agents)(see e.g. col. 15, lines 58-67). The binding reaction complexes are produced by the binding interaction between the chemical polymer of the library and a biologically active molecule of the binding reaction admixture wherein the binding interaction includes interaction such as antibodies to antigen (refers to instant claims 2, 4, 33, and 93) (see e.g. col. 2, lines 61-67; col. 3, line 26-40; col. 15, lines 15-57). The biologically active molecule can be affixed to a solid support (refers to instant claims 5, and 6) (see e.g. col. 16, lines 42-67). The solid support includes supports such as beads, and microtiter plate wells (refers to claims 3, 7-9, 19, and 20) (see e.g. col. 17, lines 11-21).

The product of Lerner et al. differs from the presently claimed invention by failing to include instructions for the use of the collection in the combination.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include instructions for the use of the collection in the combination in the

product of Lerner et al. One of ordinary skill in the art would have been motivated to include instructions for the use of the collection in the combination in the product of Lerner et al. for the advantage of providing 'information' regarding the use of the claimed combination.

Therefore, the inclusion of instructions in the kit, are mere intended use and not patentable limitation and the teachings of Lerner et al. do render the product, i.e. kit, of the instant claims *prima facie* obvious.

21. Claims 101 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower et al. (US Patent 5,639,603) and Furka et al. (WO 93/24517).

> *The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a collection of oligonucleotides. The capture agents specifically bind to preselected polypeptides and are linked directly or indirectly to a solid support that comprises optically-encoded beads. The oligonucleotides encode the preselected polypeptides and are single-stranded, double-stranded, or partially double stranded.*

Dower et al. disclose a plurality of products (see e.g. Abstract; col. 1, lines 13-21). The products include encoded synthetic chemical libraries and the binding reaction complexes (see e.g. col. 1, lines 13-21; col. 3, line 66 to col. 4, line 18; col. 4, line 66 thru col. 5, line 11; col. 26, lines 12-42). The encoded synthetic chemical libraries (refers to instant claimed set of oligonucleotide) comprise beads, identifier tags, and oligomer (see e.g. col. 3, line 66 to col. 4, line 18; col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42; col. 44, line 61 to col. 45, line 39). The identifier tags are oligonucleotides (see e.g. col. 16, lines 15-24, and lines 48-63). Each oligonucleotide tag comprises an amplification sites, monomer specific information/coding site, a spacer segment of variable length that distant the coding site from the amplification sites, and the order-of-reaction information (see e.g. col. 17, lines 42-53; col. 18, line 28 thru col. 19,

line 46). Each oligonucleotide tag has the length with a range of 50 to 150 nucleotides and is singled stranded oligonucleotide (see e.g. col. 17, lines 42-53; col. 18, lines 4-9, and lines 49-63). The oligomer comprises a plurality of different peptide sequences (see e.g. col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42). The binding reaction complexes are produced by the binding interaction between the oligomers and the receptors (refers to instant claimed collection of capture agents) such as antibodies (see e.g. col. 8, lines 23-46; col. 31, lines 11-27, and lines 36-40). The receptors are labeled with florescent tag and bind to the oligomer attached to the bead (refers to the claimed limitation of the capture agents are linked indirectly to a solid support that comprises optically-encoded beads)(see e.g. col. 31, lines 57-60). The binding reaction complexes were sorted by using fluorescence activated cell-sorting instrument (see e.g. col. 26, lines 32-40; col. 31, lines 54-63; col. 45, lines 1-7).

The product of Dower et al. differs from the presently claimed invention by failing to include the capture agents are linked directly to colored bead.

Cheung discloses micropheres and the methods of making and using the microspheres (see e.g. Abstract; col. 3, lines 28-62; col. 4, lines 39-65; col. 5, lines 3-8). The micropheres comprises markers and biomolecules (see e.g. col. 3, lines 28-62; col. 4, lines 39-65; col. 5, lines 3-8; col. 6, lines 1-68; col. 10, lines 11-28). The markers include fluorescent or dye (see e.g. col. 4, lines 39-65; col. 5, lines 3-8; col. 6, lines 61-68; col. 10, lines 11-28, and lines 65-68). The biomolecules include antibody (see e.g. col. 5, lines 3-8; col. 6, lines 61-68; col. 10, lines 11-28).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the capture agents are linked directly to colored bead as taught by Cheung in the product of Dower et al.

One of ordinary skill in the art would have been motivated to include the capture agents are linked directly to colored bead in the product of Dower et al. for the advantage of providing an increase in sensitivity and resolution of known method such as flow cytometry since both Dower et al. and Cheung disclose the use of microspheres in biological assay with techniques such as flow cytometry (Dower: col. 31, lines 50-67; Cheung: col. 10, lines 63-65).

Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Dower et al. and Cheung because Cheung disclose by examples the success in the use of antibody/fluorescent microspheres in biological assay (see e.g. col. 7, lines 33-62; col. 10, lines 33-40).

Therefore, the combine teachings of Dower et al. and Cheung do render the product of the instant claims *prima facie* obvious.

Withdrawn Rejection(s)

22. The rejections of claims 1-23, 25-37, 49-54, 93-95, and 99 under 35 USC 112, second paragraph, as being indefinite have been withdrawn in light of applicant's amendments of claims 1, 11, 23, 34, and 35.

Response to Arguments

23. Applicant's argument directed to the rejection under 35 USC 102(b) as being anticipated by Lerner et al. (US Patent 5,573,905) for claims 1-9, 11-23, 25-36, 93 and 94 was considered but they are not persuasive for the following reasons.

Applicant alleges that the teaching of Lerner et al. do not anticipate the presently claimed invention because Lerner et al. do not disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides, and the oligonucleotides of Lerner et al. are not designed to encode polypeptides. Thus, the product of Lerner et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Lerner et al. do anticipate the product, i.e. a combination, of the instant claims. It is the examiner position is that the product of Lerner et al. does anticipate the presently claimed invention.

First, Lerner et al. do disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides. Lerner et al. discloses a binding reaction admixture wherein the admixture comprises a 'mixture' of biological active molecule (refers to the instant claimed collection of capture agents) and a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides)(see e.g. col. 15, lines 34-40). Thus, Lerner et al. do disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides.

Second, the oligonucleotides of Lerner et al. are designed to encode polypeptides. Lerner et al. teaches that the unit nucleotide sequences within the oligonucleotide corresponds to the chemical unit of the polymer, i.e. each unit of nucleotide sequences corresponds to a specific amino acid in the polypeptide (see e.g. col. 5, lines 49-54; fig. 2). In figure 2, the amino acid glycine has a corresponding unit of nucleotide sequences of CACATG, and the amino acid methionine has a corresponding unit of nucleotide sequences of ACGGTA. Thus, the oligonucleotides of Lerner et al. are designed to encode polypeptides.

Therefore, the teachings of Lerner et al. do anticipate the product, i.e. a combination, of the instant claims, and the rejection is maintained.

24. Applicant's argument directed to the rejection under 35 USC 102(b) as being anticipated by Dower et al. (US Patent 5,639,603) for claims 1, 2, 11, 12, 25, 26, 36, 49-51, and 99 was considered but they are not persuasive for the following reasons.

Applicant argues that the teaching of Dower et al. do not anticipate the presently claimed invention because Lerner et al. do not disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides, and the oligonucleotides of Dower et al. are not designed to encode polypeptides. Thus, the product of Dower et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Dower et al. do anticipate the product, i.e. a combination, of the instant claims. It is the examiner position is that product of Dower et al. does anticipate the presently claimed invention.

First, Dower et al. do disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides. Dower et al. discloses a binding reaction admixture wherein the admixture comprises a 'mixture' of biological active molecule (refers to the instant claimed collection of capture agents) and a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides)(see e.g. col. 31, lines 54-60). Thus, Dower et al. do disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides.

Second, the oligonucleotides of Dower et al. are designed to encode polypeptides. Dower et al. teaches that the unit nucleotide sequences within the oligonucleotide corresponds to the

chemical unit of the polymer, i.e. each unit of nucleotide sequences corresponds to a specific amino acid in the polypeptide (see e.g. col. 18, lines 13-27; col. 45, line 62 thru col. 46, line 6). In example 1, the amino acid valine has the corresponding dinucleotide sequences of TT, and the amino acid arginine has the corresponding unit of nucleotide sequences of TA (see e.g. col. 45, line 62 thru col. 46, line 6; col. 46, lines 47-67). Thus, the oligonucleotides of Dower et al. are designed to encode polypeptides.

Therefore, the teachings of Dower et al. do anticipate the product, i.e. a combination, of the instant claims, and the rejection is maintained.

25. Applicant's argument directed to the rejection under 35 USC 103(a) as being unpatentable over Lerner et al. (US Patent 5,573,905) and Dower et al. (US Patent 5,639,603) for claims 1-9, 11-23, 25-36, 49-51, and 93-95 was considered but they are not persuasive for the following reasons.

Applicant contends that the combine teaching of Lerner et al. and Dower et al. is not obvious over the presently claimed invention because neither Lerner et al. nor Dower et al. disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides, and the oligonucleotides of both Lerner et al. and Dower et al. are not designed to encode polypeptides. Thus, the combine teaching of Lerner et al. and Dower et al. is not obvious over the presently claimed invention.

Applicant's arguments are not convincing since the combine teachings of Lerner et al. and Dower et al. do render the product of the instant claims *prima facie* obvious. It is the

examiner position that the combine teaching of Lerner et al. and Dower et al. is obvious over the presently claimed invention.

First, both Lerner et al. and Dower et al. do disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides. Lerner et al. discloses a binding reaction admixture wherein the admixture comprises a 'mixture' of biological active molecule (refers to the instant claimed collection of capture agents) and a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides)(see e.g. col. 15, lines 34-40). Dower et al. discloses a binding reaction admixture wherein the admixture comprises a 'mixture' of biological active molecule (refers to the instant claimed collection of capture agents) and a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides)(see e.g. col. 31, lines 54-60). Thus, both Lerner et al. and Dower et al. do disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides.

Second, of both Lerner et al. and Dower et al. are designed to encode polypeptides. Lerner et al. teaches that the unit nucleotide sequences within the oligonucleotide corresponds to the chemical unit of the polymer, i.e. each unit of nucleotide sequences corresponds to a specific amino acid in the polypeptide (see e.g. col. 5, lines 49-54; fig. 2). In figure 2, the amino acid glycine has a corresponding unit of nucleotide sequences of CACATG, and the amino acid methionine has a corresponding unit of nucleotide sequences of ACGGTA. Dower et al. teaches that the unit nucleotide sequences within the oligonucleotide corresponds to the chemical unit of the polymer, i.e. each unit of nucleotide sequences corresponds to a specific amino acid in the polypeptide (see e.g. col. 18, lines 13-27; col. 45, line 62 thru col. 46, line 6). In example 1, the

amino acid valine has the corresponding dinucleotide sequences of TT, and the amino acid arginine has the corresponding unit of nucleotide sequences of TA (see e.g. col. 45, line 62 thru col. 46, line 6; col. 46, lines 47-67). Thus, the oligonucleotides of both Lerner et al. and Dower et al. are designed to encode polypeptides.

Therefore, the combine teachings of Lerner et al. and Dower et al. do render the product of the instant claims *prima facie* obvious, and the rejection is maintained.

26. Applicant's argument directed to the rejection under 35 USC 103(a) as being unpatentable over Lerner et al. (US Patent 5,573,905) and Iris et al. (US Patent 6,403,309 B1) for claims 1-9, 11-23, 25-36, 49-54, and 93-95 was considered but they are not persuasive for the following reasons.

Applicant alleges that the combine teaching of Lerner et al. and Iris et al. is not obvious over the presently claimed invention because neither Lerner et al. nor Iris et al. disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides, and the oligonucleotides of both Lerner et al. and Iris et al. are not designed to encode polypeptides. Thus, the combine teaching of Lerner et al. and Iris et al. is not obvious over the presently claimed invention.

Applicant's arguments are not convincing since the combine teachings of Lerner et al. and Iris et al. et al. do render the product of the instant claims *prima facie* obvious. It is the examiner position that the combine teaching of Lerner et al. and Iris et al. is obvious over the presently claimed invention.

First, Lerner et al. do disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides. Lerner et al. discloses a binding reaction admixture wherein the admixture comprises a 'mixture' of biological active molecule (refers to the instant claimed collection of capture agents) and a 'mixture' of the encoded combinatorial library (refers to the instant claimed collection of oligonucleotides)(see e.g. col. 15, lines 34-40). Thus, Lerner et al. do disclose a combination of two collections, i.e. a collection of capture agents and a collection of oligonucleotides.

Second, Lerner et al. are designed to encode polypeptides. Lerner et al. teaches that the unit nucleotide sequences within the oligonucleotide corresponds to the chemical unit of the polymer, i.e. each unit of nucleotide sequences corresponds to a specific amino acid in the polypeptide (see e.g. col. 5, lines 49-54; fig. 2). In figure 2, the amino acid glycine has a corresponding unit of nucleotide sequences of CACATG, and the amino acid methionine has a corresponding unit of nucleotide sequences of ACGGTA. Thus, the oligonucleotides of Lerner et al. are designed to encode polypeptides.

Therefore, the combine teachings of Lerner et al. and Iris et al. do render the product of the instant claims *prima facie* obvious, and the rejection is maintained.

Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
November 3, 2005

PONNALURI
PRIMARY EXAMINER